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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,871	06/20/2003	R. Glen Coleman	PD-170.02	6659
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER CHENG, JACQUELINE	
			ART UNIT	PAPER NUMBER
			3768	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/600,871

Applicant(s)

COLEMAN, R. GLEN

Examiner

JACQUELINE CHENG

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

2. Claims 1, 5, 6, 9, and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, and 15 of U.S. Patent No. 6,361,531 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose substantially the same subject matter of an US emitting member emitting US energy at a predetermined distance with a handle to create a lesion in tissue.

3. Claims 21 and 24-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 10, 12, 17, 18, 19, and 20 of U.S. Patent No. 6,409,720 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose substantially the same subject matter of a method for creating lesion in tissue of a patient by emitting US energy and focusing the energy at a plurality of focusing zones.

4. Claims 21-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 4, 5, 10, 11, 19, 28, 38, and 39 of U.S. Patent No. 6,413,254 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose substantially the same subject matter of a method for

creating a lesion in a tissue by focusing ultrasonic ablation energy using electric signal supplied to piezoelectric transducers.

5. Claims 21 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-11, and 17-23 of U.S. Patent No. 6,451,013 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose substantially the same subject matter of a method for positioning an US emitting member adjacent to tissue and emitting and focusing the energy at a plurality of focusing zones in the tissue and heating the tissue to create lesions.

6. Claims 21, 24, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-10, 15, and 16 of U.S. Patent No. 6,595,934 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose substantially the same subject matter of a method for creating a plurality of lesions at a plurality of focusing zones by emitting US energy at the focusing zones.

7. Claim 21, 24, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 10, 13-15, 19, and 22-24 of U.S. Patent No. 6,936,046 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose substantially the same subject matter of a method for positioning a US adjacent to a tissue, and emitting US energy at a plurality of spaced focusing zones and heating the tissue to create lesions in the area.

Art Unit: 3737

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 1, 2, 4, 6, 9-12, 14, 16, 18, 21-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker (US 6,508,774 B1). Acker discloses applying high intensity focused ultrasound (HIFU) at tissue in order to heat tissue to a temperature sufficient to destroy unwanted tissue such as by creating lesions (col. 1 line 19-35, col. 2 line 49-56). The HIFU apparatus of Acker has a structural element (fig. 1 element 76) to hold the ultrasound emitting members in a predetermined spatial relationship with one another. The particular shape of the body and the structural element may be varied in a known manner, in particular the structure could contain an arm, which the surgeon would use to move the ultrasound apparatus into place (a handle) such as disclosed in the incorporated reference WO/98/52465 (col. 7 line 21-43, col. 1 line 36-39 of Acker, fig. 5 element 17 of WO/98/52465). The ultrasound emitting member can comprise of a plurality of individual piezoelectric ultrasonic transducers (fig. 1 elements 64a-64c, col. 6 line 61-65) which are independently actuatable and non-actuatable as each transducer has an individual channel and a processor that generates individual waveforms for each channel (col. 5 line 60-67, col. 6 line 50-55). If a relatively large region of tissue needs to be heated (fig. 1 element R) then ultrasonic energy can be applied at numerous focal points (fig. 1 elements F, F', F''). In the system of Acker sets of transducers can be chosen to focus on the various regions depending on which transducers have good acoustic paths. For example if only transducer element 64b has a good path to focus point F, only transducer element 64c has a good path to

focus point F', and only transducer element 64a has a good path to focus point F'', then each transducer would be selectively, independently actuated in order to apply sonic energy along the desired path of F, F', and F'' (col. 10 line 21-43, col. 11 line 52 - col. 12 line 6, col. 12 line 38-43). Depending on what the area of region to be ablated is depends on the path and focal regions that are chosen. It would therefore be obvious to one skilled in the art to have either a continuous lesion, discontinuous lesion, or a plurality of disconnected lesion segments depending on the focal points chosen.

10. **Claims 5, 13, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker as applied to claims 1 and 9 above, and further in view of Weng'855. (U.S. Patent No. 6,626,855). Acker teaches the present claimed invention as discussed above except for the malleability of the handle shaft of the ultrasound therapeutic device. Figure 3C of Weng'855 diagrams the flexible portion (ref. no. 31) of the handle shaft. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the held-held ultrasonic applicator with the flexible handle shaft of Weng'855 because Acker teaches that any particular shape and/or body element well known in the art can be used and also having the flexibility or malleability of the handle shaft allows for better maneuverability of the device to different regions of interest as taught by Weng'855 (see col. 10, lines 43-49).

11. **Claims 7, 8, 19, 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker as applied to claims 1 and 9 above, and further in view of Castel (U.S. Patent No. 5,413,550).

Art Unit: 3737

Acker discloses the claimed invention as discussed above except for the specifics of the handle of the ultrasound therapeutic device. Acker also teaches that any configuration of the device that is well known in the art can be used such as the device as disclosed in Castel. Figure 2 of Castel diagrams the specifics of the handle as disclosed in Applicant's claims. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the ultrasonic applicator with the control features of Castel because the graspable handle with control switches or buttons allows for quicker and thus better control of the therapeutic procedure, which is a well known expedient in the art.

12. **Claims 3 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker as applied to claims 1 and 9 above, and further in view of Weng'694 (US 6,719,694 B2). Acker discloses the claimed invention as discussed above except for the specifics of the ultrasonic transducer element shapes. It would be obvious to use any transducer element that is well known in the art such as disclose by Went'694. Weng '694 discloses that a single transducer element can be curved (col. 11 line 34-40, fig. 18a element 231)

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.
14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit
3737

/Jacqueline Cheng/
Examiner, Art Unit 3768